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| Policy & Procedure Title | Storage and Handling-Cold Chain Failure | Issuing Date | 07/17/2012 |
| Policy & Procedure Number | 11 | Revision Date | 07/03/2018 |
| Policy & Procedure Approval Authority | <i>Dave McConnick</i> | | |

Policy & Procedure Summary

Vaccines must be stored properly from the time they are manufactured, throughout the delivery process and until the time they are administered. Failure to maintain the cold-chain of vaccines due to shipping delays, power outages, equipment failure and human error may cause vaccines to become ineffective.

Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing vaccine cold chain failure. It replaces the following policies:

Title of Policy: **Vaccine Cold Chain Failure: Procedures and Corrective Action**
 Policy Number: III-03
 Creation Date: February 18, 2009
 Revision Date: March 2011

If any vaccine is determined to have exceeded the established temperature ranges or storage and handling requirements, steps must be **immediately** taken to ensure the viability of all vaccine. The following procedures and corrective actions should be followed to resolve vaccine cold-chain failures:

- Correct improper storage and handling conditions, including exposure to light and storage temperatures that are outside of the established range.
- Check all digital data loggers for correct placement and operation. Document any temperature fluctuation and the amount of time that vaccines were out of the correct temperature range.
- If vaccine shipping or storage temperatures are recorded **above** or **below** the required range, do not use the vaccine until the viability of the vaccine has been established by the vaccine manufacturer. Place the vaccine in the refrigerator or freezer, depending on the proper storage requirements, and clearly mark the vaccine "Not for Use".
- When receiving vaccine shipments, if any damage, excessive shipping time, cold chain breach has occurred, provider must notify the Indiana Immunization Program within **two hours** of vaccine delivery.
- If the storage unit's ability to maintain the recommended temperatures is in question and the problem persists for over two hours, move vaccines to a pre-established back-up location to maintain the cold-chain.
 - All providers must have written emergency procedures for proper handling of publicly funded vaccines in the event of power or equipment failure. **See the Storage and Handling - Emergency Plans Policy for complete information on emergency procedures.**
- If vaccines are determined to have exceeded designated storage temperatures, providers **MUST** contact the manufacturer and obtain guidance and recommendations for vaccine viability.
 - Providers should report all incidents of vaccine cold-chain failure within 24 hours to the Immunization Division (800)-701-0704.
 - A Vaccine Return transaction should be completed and submitted in VOMS, when available (or submit State Form 54052 in the interim), for all vaccines determined to be non-viable by the Immunization Division.

After a temperature excursion, proof of at least 5 days of in-range temperatures need to be provided to ISDH to establish that the unit is stable and operating properly. A root-cause analysis (RCA) to find out why the excursion occurred is also required. Additional days-in-range reports may be required depending upon the reason for the temperature excursion.

Providers should never discard or return any vaccine unless they are instructed to do so by the Immunization Division.

The Immunization Division has developed a visual Refrigerator/Freezer Temperature Log to assist providers in tracking storage unit temperatures in order to determine if there has been a temperature excursion. By using this visual temperature log, providers can easily track storage unit temperatures in either Celsius (C°) or Fahrenheit (F°).

Refrigerator Temperature Log

Record temperatures twice (2x) a day.

1. Write your initials and the time of day.
2. Place an "X" next to the current temperature. **Aim for 40°F/4°C (Yellow bar)**
3. If the temperature is too warm or too cold, follow the actions steps listed on reverse side.
4. At the end of the month, file this log and save for 3 years.

Days 16 – 31 Month/Year _____

Unit Name/Location _____

Thermometer type: ☐ °F (Fahrenheit) ☐ °C (Celsius)

| Day of Month | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|--|-------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Staff Initials | | | | | | | | | | | | | | | | |
| Time | | | | | | | | | | | | | | | | |
| Min/Max Temp | | | | | | | | | | | | | | | | |
| Refrigerator Temperatures | | | | | | | | | | | | | | | | |
| ≥49°F | ≥10°C | | | | | | | | | | | | | | | |
| 48°F | 9°C | | | | | | | | | | | | | | | |
| 47°F | | | | | | | | | | | | | | | | |
| Danger! Temperatures above 46°F/8°C are too warm! Immediately follow the action steps listed on reverse side.* | | | | | | | | | | | | | | | | |
| 46°F | 8°C | | | | | | | | | | | | | | | |
| 45°F | 7°C | | | | | | | | | | | | | | | |
| 44°F | 6°C | | | | | | | | | | | | | | | |
| 43°F | | | | | | | | | | | | | | | | |
| 42°F | 5°C | | | | | | | | | | | | | | | |
| 41°F | | | | | | | | | | | | | | | | |
| 40°F | 4°C | | | | | | | | | | | | | | | |
| 39°F | | | | | | | | | | | | | | | | |
| 38°F | 3°C | | | | | | | | | | | | | | | |
| 37°F | | | | | | | | | | | | | | | | |
| 36°F | 2°C | | | | | | | | | | | | | | | |
| Danger! Temperatures below 36°F/2°C are too cold! Immediately follow the action steps listed on reverse side.* | | | | | | | | | | | | | | | | |
| 35°F | 1°C | | | | | | | | | | | | | | | |
| 34°F | | | | | | | | | | | | | | | | |
| 33°F | | | | | | | | | | | | | | | | |
| ≤32°F | ≤0°C | | | | | | | | | | | | | | | |

ISDH Immunization Program Toll Free Number: (800) 701-0704

*Record problem, Actions taken and Outcome on reverse side.

The temperature log directs providers to record problems on the reverse side of the log. Providers should document all actions taken and outcomes if temperatures are recorded above or below the required temperature range.

Actions Steps

1. Store vaccine under proper conditions as quickly as possible.
2. Call the vaccine manufacturer(s) (for Direct Ship Vaccines) to determine if vaccine can still be used.
3. Call your ISDH Field Representative.
4. Record problem, actions taken and outcomes below.

| Date/Time & Initials | Problem (Too Warm, Too Cold, Power Failure, etc.) | Actions Taken | Outcome |
|----------------------|--|---------------|---------|
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**Manufacturer Quality Control
Office Telephone Numbers**

| Manufacturer/ Distributor | Telephone Number | Products |
|--|--|---|
| GlaxoSmithKline | (Vaccine Service Center) (866) 475-8222 (888) 593-5977 | Bexsero® Boostrix® Cervarix® Engerix-B® Fluarix® FluLaval® Havrix® Hiberix® Infranix® Knrix® MEN-HIBRIX® Menveo® Pediarix® Rolanix® Twinrix® |
| MedImmune, Inc. | (877) 358-6478 (LAIV customer support) (877) 633-4411 (General customer support) | Flukmist® |
| Merck | (Health Care Professional) (800) 609-4618 (Adverse Reactions) (800) 672-6372 (Vaccine Customer Care) (877) 829-6372 | Gardasil® 9 MMRii® Pedvax-Hib® Pneumovax® ProQuad® Recombyx-HB® RotaTeq® VAQTA® Varivax® Zostavax® |
| Sanofi Pasteur | (800) 822-2463 | ActHib® Adacel® Daptacel® DT (Generic) FluZone® IPOL® Menactra® Pentacel® Tenivac® |
| Pfizer | (800) 879-3477 | Prevnar™ TRUMENBA® |
| Centers for Disease Control & Prevention Drug Service | (770) 488-7100 (404) 639-3717 | Distributor for Diphtheria antitoxin |
| Talecris Biotherapeutics | (919) 553-5011 (800) 520-2807 | HBIG, IGIM, RIG, TIG |
| Biotech Pharmaceuticals | (800) 458-4244 | HBIG |

The log also provides the Vaccine Manufacturer contact information to assist providers if calls must be made to the manufacturer to determine vaccine viability.

Procedure Details

Step 1) Providers should monitor the storage and handling of all vaccines

Step 2) If concerns exist regarding the cold-chain of vaccines due to shipping delays, power outages, equipment failure and human error, providers should take the necessary steps to ensure the viability of all vaccines in question.

Step 3) Providers should document all steps taken on the reverse side of the Refrigerator/Freezer Temperature Log.

Step 4) If necessary, providers should contact the vaccine manufacturer and the Immunization Division to determine viability.

Step 5) If necessary, providers should complete and submit the Vaccine Return form to the Immunization Division.

References & Resources

Refrigerator/Freezer Temperature Log

Storage and Handling-Emergency Plan Policy (17)

Revision History

07/17/2012, Created
03/01/2014, Revised
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